Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2007-03

Re-evaluation of Fenbutatin Oxide

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated fenbutatin oxide. The PMRA is proposing that fenbutatin oxide is acceptable for continued registration. Additional mitigation measures to further protect workers and the environment are identified in this document. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing fenbutatin oxide with specific direction on how to address these measures and requirements.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for fenbutatin oxide. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications at the address below.

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1.0 Background

Health Canada's Pest Management Regulatory Agency (PMRA) is re-evaluating all pesticides, both active ingredients and formulated end-use products, that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Fenbutatin oxide has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under Program 1, the PMRA relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents, to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews, the PMRA will propose, under Program 1, a regulatory decision and appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of fenbutatin oxide and concluded that, on the basis of health and environmental risk assessments, it was eligible for reregistration with implementation of mitigation measures. These conclusions were published in a 1994 RED document and a 2002 Tolerance Reassessment Eligibility Decision (TRED) document for fenbutatin oxide. In its re-evaluation of fenbutatin oxide, the PMRA based its conclusions on both these documents, taking into account the Canadian use pattern and issues (e.g., the federal Toxic Substances Management Policy). A review of the chemistry of Canadian products was also conducted.

2.0 Re-evaluation of Fenbutatin Oxide

Active substance:	Fenbutatin oxide
Common name:	Fenbutatin oxide
Chemical name:	hexakis(2-methyl-2-phenylpropyl)distannoxane
IUPAC:	bis[tris(2-methyl-2-phenylpropyl)tin] oxide
CAS:	hexakis(2-methyl-2-phenylpropyl)distannoxane
CAS number:	13356-08-6

In Canada, fenbutatin oxide was first registered in 1977. According to current end-use product labels, this active ingredient is registered in Canada for use in greenhouse food and non-food crops (tomatoes, cucumbers and ornamentals/nursery stock) as well as terrestrial non-food crops

(ornamentals and nursery stock) to control spider mites. Canadian products containing fenbutatin oxide are listed in Appendix I.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for fenbutatin oxide is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are presented in the RED for fenbutatin oxide.

The federal Toxic Substances Management Policy and Regulatory Directive DIR99-03 were taken into consideration during the review of fenbutatin oxide, and it was concluded that fenbutatin oxide is not a candidate for Track 1 classification. The technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or Toxic Substances Management Policy Track 1 substances as identified in Appendix II of DIR99-03.

3.0 Proposed Re-evaluation Decision

The USEPA published the RED for fenbutatin oxide addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of fenbutatin oxide that are also registered in Canada. The PMRA is proposing that fenbutatin oxide is acceptable for continued registration with additional mitigation measures specified in Section 4.0 of this PACR.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision. Registrants of products containing fenbutatin oxide should not apply for label amendments or submit the additional data as described in Section 5.0 during this comment period; they will be informed by letter of the specific instructions for addressing label changes and data requirements once the re-evaluation decision has been finalized.

4.0 Proposed Regulatory Actions

Canadian end-use product labels should be amended to include the following statements to further protect workers and the environment.

In the **PRECAUTIONS** section of the secondary display panel:

- "Wear a long-sleeved shirt and long pants, shoes plus socks and chemical-resistant gloves during application. In addition, wear a NIOSH-approved respirator and goggles during application with handheld equipment, or during mixing and loading, clean-up or repair activities. Also, wear chemical-resistant headgear during overhead application."

- "It is recommended that this product not be applied in a way that will contact workers or other persons, either directly or through drift. Only handlers wearing personal protective equipment may be in the area during application."

- "Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet."

- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

- "Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

- "If this pest control product is to be used on a commodity that may be exported to the U.S. and you require information on acceptable residue levels in the U.S. contact 1-866-375-4648 or www.croplife.ca."

In the **DIRECTIONS FOR USE** section of all Canadian end-use product labels:

- "Do not enter or allow entry into treated areas within 12 hours of application. For hand activities involving high foliar contact, do not enter treated areas to perform such work until at least 48 hours have passed since application."

In the **DIRECTIONS FOR USE** section of Canadian labels of products with outdoor uses:

- "DO NOT apply this product by air."

- "Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the ASAE medium classification."

- **Buffer zones:**

  "The buffer zones specified in the table hereafter are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats".

Method of Application	Buffer Zone (metres) Required for the Protection of Aquatic Habitats at Water Depths of:		
	< 1 m	1–3 m	> 3 m
Field sprayer	55	20	10
Field sprayer with shrouds	15	5	3
Field sprayer with cones	40	15	5

- "Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet."

- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

- "Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

- "If this pest control product is to be used on a commodity that may be exported to the U.S. and you require information on acceptable residue levels in the U.S. contact 1-866-375-4648 or www.croplife.ca."

In the **DIRECTIONS FOR USE** section of all Canadian end-use product labels:

- "Do not enter or allow entry into treated areas within 12 hours of application. For hand activities involving high foliar contact, do not enter treated areas to perform such work until at least 48 hours have passed since application."

In the **DIRECTIONS FOR USE** section of Canadian labels of products with outdoor uses:

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	< 1 m	1 - 3 m	> 3 m
Field sprayer	55	20	10
Field sprayer with shrouds	15	5	3
Field sprayer with cones	40	15	5

- "When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture".

- "DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes".

In the **ENVIRONMENTAL HAZARDS** section of the secondary display panel of all Canadian product labels:

- "Do not allow effluent from greenhouses containing this product to enter lakes streams, ponds or other waters. For guidance, contact the provincial regulatory agency."

In the **ENVIRONMENTAL HAZARDS** section of the secondary display panel of products for outdoor use:

- "TOXIC to aquatic organisms. Observe buffer zones specified under **DIRECTIONS FOR USE**."

- "To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g., soils that are compacted, fine textured or low in organic matter such as clay)".

- "Avoid application of this product when heavy rain is forecast".

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the aforementioned label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

4.1 Maximum Residue Limits

There are no dietary concerns regarding the use of fenbutatin oxide on food and feed crops reported in the USEPA RED. This document adequately addresses the Canadian dietary exposure from domestic and imported foods.

Fenbutatin oxide is currently registered in Canada for use on greenhouse tomatoes and cucumbers.

As noted, fenbutatin oxide may be used in other countries on other crops imported into Canada.

The maximum residue limits (MRLs) for fenbutatin oxide are established for the following commodities:

- apples, pears at 3 ppm;
- cucumbers, tomatoes at 0.5 ppm; and
- citrus fruits at 2 ppm.

Residues of fenbutatin oxide in all other agricultural commodities, including those approved for treatment in Canada are regulated by subsection B.15.002(1), where no specific MRL for a pest control product has been established in the Food and Drug Regulations, subsection B.15.002(1) applies. This requires that residues do not exceed 0.1 ppm and has been considered a general MRL for enforcement purposes. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be promulgated.

5.0 Data Requirements

Registrants should note that specific data, which were selected from the data package submitted to the USEPA to support reregistration of this active ingredient, may be required by the PMRA in the future with respect to use expansions, special reviews or minor uses, or to establish MRLs.

6.0 Supporting Documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document (*Fenbutatin-oxide*) Re-registration Eligibility Decision is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

The USEPA TRED document for fenbutatin oxide is available on the Office of Pesticide Programs' website at www.epa.gov/REDs/fenbutatinoxide_tred.pdf

Appendix I Products Containing Fenbutatin Oxide Registered in Canada as of 1 June 2005

Product Name	Registrant	Registration Number	Guarantee	Class
Technical Fenbutatin-oxide	E.I. DuPont Canada Company	18594	98%	Technical
Vendex 50WP Miticide	E.I. DuPont Canada Company	16162	50%	Commercial
Vendex 50W Wettable Powder Miticide	Plant Products Co. Ltd.	16309	50%	Commercial

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